

## REMARKS

**Status of the Claims**

Claims 13-24 are currently pending.

**Double Patenting Rejection**

The applicants respectfully disagree that claim 19 of the present application and claim 7 of prior U.S. Patent 6,379,680 are "coextensive in scope" as is required to make a statutory double patenting rejection. The chart below should served to illustrate the differences:

| Claim 19 of present application (which further limits claim 13)                                                                                                                        | Claim 7 of U.S. Patent 6,379,680 (which further limits claim 1)                                                                                                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 13. An emulsifier-free cosmetic or dermatological preparation, which preparation is a finely dispersed water-in-oil system, said preparation comprising                                | 1. An emulsifier-free cosmetic or dermatological preparation, which preparation is a finely dispersed water-in-oil system, said preparation comprising         |
| a) an oil phase;                                                                                                                                                                       | a) an oil phase;                                                                                                                                               |
| b) an aqueous phase; and                                                                                                                                                               | b) an aqueous phase; and                                                                                                                                       |
| c) micronized, inorganic pigment particles positioned at an interface of said oil phase and said aqueous phase, said micronized, inorganic pigment particles being metal oxides which: | c) micronized, inorganic pigments particles positioned at an interface of said oil phase and said aqueous phase, said micronized, inorganic pigment particles: |
| i) have an average particle size of less than 200 nm;                                                                                                                                  | i) have an average particle size of less than 200 nm;                                                                                                          |
| ii) have both hydrophilic and lipophilic properties resulting in an amphiphilic character; and                                                                                         | ii) have both hydrophilic and lipophilic properties resulting in an amphiphilic character; and                                                                 |
| (wherein the metal oxides used are titanium dioxide particles coated with simethicone and alumina) - limitation of claim 19                                                            | iii) <b>selected from the group consisting of metal oxides, which are coated on the surface thereof with:</b>                                                  |
|                                                                                                                                                                                        | (A) a dimethylpolysiloxane and/or silica gel; and                                                                                                              |
|                                                                                                                                                                                        | (B) aluminium hydroxide and/or alumina and/or silicon dioxide; (metal oxide is titanium oxide coated with simethicone and alumina)                             |
|                                                                                                                                                                                        | and                                                                                                                                                            |
| d) optionally cosmetic or pharmaceutical auxiliaries, additives and/or active substances.                                                                                              | d) optionally cosmetic or pharmaceutical auxiliaries, additives and/or active substances.                                                                      |

The key difference is that the '680 patent is narrower in scope with regard to what can be coated on the metal oxide, i.e. limitation iii. highlighted in bold text. While both claim 19 as whole and claim 7 as a whole both have the same limitation of "titanium oxide coated with simethicone and alumina", claim 7 of the '680 patent is limited as to the scope as to what other coatings may be present whereas claim 19 is not so limited.

The applicants also respectfully disagree that claim 23 of the present application and claim 9 of prior U.S. Patent 6,558,683 are "coextensive in scope" as is required to make a statutory double patenting rejection. The chart below should served to illustrate the differences:

| Claim 23 of present application (which further limits claim 13)                                                                                                                                                                                                                                         | Claim 9 of U.S. Patent 6,558,683 (which further limits claim 1)                                                                                                                                                                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 23. A process for preparation the emulsifier-free cosmetic or dermatological preparation of claim 13, said process comprising:                                                                                                                                                                          | 9. A process for preparing the emulsifier-free cosmetic or dermatological preparation of claim 1, said process comprising:                                                                                                                                                                       |
| a) dispersing an amphiphilic inorganic pigment particles of claim 13 in an oil phase to form a mixture of said micronized inorganic pigment particles and said oil phase, said oil phase optionally comprising one or more cosmetic or pharmaceutical auxiliaries, additives and/or active ingredients; | a) dispersing an amphiphilic inorganic metal oxide pigment in an oil phase to form a mixture of said amphiphilic inorganic metal oxide pigment and said oil phase, said oil phase optionally comprising one or more cosmetic or pharmaceutical auxiliaries, additives and/or active ingredients; |
| b) homogenizing said mixture by uniform stirring and, optionally, heating; and                                                                                                                                                                                                                          | b) homogenizing said mixture by uniform stirring and, optionally, heating; and                                                                                                                                                                                                                   |
| c) during said homogenizing, mixing an aqueous phase with said mixture, said aqueous phase also optionally comprising one or more cosmetic or pharmaceutical auxiliaries, additives and/or active ingredients.                                                                                          | c) during said homogenizing, mixing an aqueous phase with said mixture, said aqueous phase also optionally comprising one or more cosmetic or pharmaceutical auxiliaries, additives and/or active ingredients.                                                                                   |
| 13. An emulsifier-free cosmetic or dermatological preparation, which preparation is a finely dispersed water-in-oil system, said preparation comprising                                                                                                                                                 | 1. An emulsifier-free cosmetic or dermatological preparation, which preparation is a finely dispersed oil-in-water system, said preparation comprising                                                                                                                                           |
| a) an oil phase;                                                                                                                                                                                                                                                                                        | a) an oil phase;                                                                                                                                                                                                                                                                                 |
| b) an aqueous phase; and                                                                                                                                                                                                                                                                                | b) an aqueous phase; and                                                                                                                                                                                                                                                                         |
| c) micronized, inorganic pigment particles positioned at an interface of said oil phase and said aqueous phase, said micronized, inorganic pigment particles being metal oxides which:                                                                                                                  | c) micronized, inorganic pigments particles positioned at an interface of said oil phase and said aqueous phase, said micronized, inorganic pigment particles being metal oxides which:                                                                                                          |
| i) have an average particle size of less than 200 nm;                                                                                                                                                                                                                                                   | i) have an average particle size of less than 200 nm;                                                                                                                                                                                                                                            |
| ii) have both hydrophilic and lipophilic properties resulting in an amphiphilic character; and                                                                                                                                                                                                          | ii) have both hydrophilic and lipophilic properties resulting in an amphiphilic character; and                                                                                                                                                                                                   |
| d) optionally cosmetic or pharmaceutical auxiliaries, additives and/or active substances.                                                                                                                                                                                                               | d) optionally cosmetic or pharmaceutical auxiliaries, additives and/or active substances.                                                                                                                                                                                                        |

Claim 9 is necessarily of different scope that claim 23 as it is directed toward make an oil-in-water system vs. the water-in-oil system of claim 23 (see highlighted text above).

**Obviousness-type double patenting rejections**

The applicants have filed a terminal disclaimer over the parent (SN: 09/367,365) for this application. If the Examiner has access to the prosecution history of that application, terminal disclaimers were filed over all of the application serial numbers which constitute the patents cited in the Examiner's double patenting rejection (see the chart below):

| U.S. Patent cited | Application Serial Number      | T.D. filed in SN: 09/367,365? |
|-------------------|--------------------------------|-------------------------------|
| 6,582,707         | 09/389,129                     | YES                           |
| 6,585,983         | 09/388,717                     | YES                           |
| 6,579,529         | 09/396,557                     | YES                           |
| 6,410,035         | 09/389,684                     | YES                           |
| 6,391,321         | 09/396,918                     | YES                           |
|                   | 10/081,618 (DIV of 09/389,684) | YES<br>for 09/389,684         |
|                   | 10/081,613 (DIV of 09/396,918) | YES<br>for 09/396,918         |

No additional terminal disclaimers are necessary because this application has been terminally disclaimed over the parent application SN: 09/367,365 which in turn terminally disclaimed over the application serial numbers which constituted the patents and applications cited in the Examiner's double patenting rejection. Therefore, the patent term from this application cannot run longer than what has been established by the previous terminal disclaimer filings.

**Closing**

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

Norris, McLaughlin & Marcus, P.A.

By: Howard C. Lee  
Howard C. Lee  
Reg. No. 48,104

220 East 42<sup>nd</sup> Street  
30<sup>th</sup> Floor  
New York, New York 10017  
(212) 808-0700

**CERTIFICATE OF FACSIMILE TRANSMISSION**

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 (7 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 29 April 2004

By: Agata Gliniska  
Agata Gliniska